

**Notice of Allowability**

Application No.

09/939,709

Examiner

Joseph T. Voitach

Applicant(s)

BARON ET AL.

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 10/27/2004.
2. ☒ The allowed claim(s) is/are 23, 24 and 31-50.
3. ☒ The drawings filed on 28 August 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
  - \* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

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### **DETAILED ACTION**

This application filed August 28, 2001 claims benefit to provisional application 60/228,450, filed August 29, 2000.

Applicants' amendment filed October 27, 2004, has been received and entered. Claims 1-22 and 25-30 have been cancelled. Claims 23 and 45 have been amended. Claims 48-50 have been added. Claims 23, 24 and 31-50 are pending.

### ***Election/Restriction***

Applicant's election with traverse of Group IV, in Paper No. 16 was acknowledged. The election of species was withdrawn. Newly added claims 48-50 are drawn to the elected invention. Applicants have not provided any new arguments in traverse of the restriction requirement, therefore the requirement is still deemed proper.

Claims 23, 24 and 31-50 are pending. Claims 23, 24, 31-50, drawn to a method of identifying genes which are modulated by  $\Delta$ FosB are currently under examination.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 34, 35, 46 and 47 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

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Applicants note the teachings of the specification for making abstracts and argue that the language of the claim would be understood by the skilled artisan and is not indefinite citing MPEP 2173.02 in support of their arguments.

Examiner has reviewed the specification and considered Applicants arguments, and found them persuasive. One of skill in the art would know what is meant and encompassed by the claims, in particular for the use of various types of lysates for specific types of assays/methodology.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23, 24, 31, 32, 36-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Nestler *et al.* (IDS reference) is withdrawn.

The amendments to the claims has differentiated the claimed invention from that taught by Nestler *et al.* More specifically, as noted by Applicants, Nestler *et al.* does not teach to use cells associated with osteogenesis or adipogenesis. To the contrary, Nestler *et al.* teach that despite high expression of FosB in bone tissues no abnormal pathology nor development is seen (see for example summary in first paragraph of abstract). Given this teaching, one would not

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expect that practicing the methods taught by Nestler *et al.* would even inherently result in the identification of genes associated with osteogenesis or adipogenesis.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 23, 31, 33, 34, 35, 45, 46 and 47 rejected under 35 U.S.C. 103(a) as being unpatentable over Nestler *et al.* and Agamemnon *et al.* is withdrawn.

As discussed above, Applicants argue that Nestler *et al.* does not teach to use cells associated with osteogenesis or adipogenesis, or to identify genes associated with osteogenesis or adipogenesis in these cells. Further, Agamemnon *et al.* fail to teach that the FosB mice demonstrated phenotypes associated with osteogenesis and/or adipogenesis.

### ***Reasons for Allowance***

The following is an examiner's statement of reasons for allowance:

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Applicants' arguments and amendments to the claims have obviated the rejections of record. As discussed above, Nestler *et al.* does not teach to use cells associated with osteogenesis or adipogenesis, or to identify genes associated with osteogenesis or adipogenesis in these cells. Importantly, Agamemnon *et al.* teaches that FosB mice demonstrated no phenotypes associated with osteogenesis and/or adipogenesis. The teachings of Agamemnon *et al.* for a role of FosB in bone is consistent with that known in the art at the time of filing. For example Jochum *et al.* (US Patent 6,653,064) teach that mice expressing high levels of FosB "in bone tissue show no skeletal phenotype" (paragraph 16), and mice lacking FosB demonstrated not obvious phenotype (Guda *et al.* Oncogene 1996). The present specification is the first to provide evidence for a role of FosB in osteogenesis and adipogenesis.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

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